REMARKS

Claims 1-18 and 20 have been amended to more clearly define the invention and to place the claims in accordance with U.S. patent practice. Claim 1 was amended to delete the Markush grouping of dispersing agents from element (a)(iv). Support for amended claim 1 is found in the specification on page 7, line 28-page 8, line 3. Claims 12 and 13 have been amended to recite the excipients from which the polymer in the liquid medium and the dispersing agent can be selected. Support for amended claims 12 and 13 is found in the specification on page 8, line 27, to page 10, line 6. Additionally, the dependencies of claims 10-18 and 20 have been amended to remove improper multiple dependencies. These claims now only depend upon claims 1-9.

New claims 21-23 have been added. Claim 21 is directed to a preferred embodiment of the invention deleted from amended claim 10. New claims 22 and 23 are directed to an embodiment of the invention further comprising a plasticizer, and are supported by page 10, lines 8-14, of the specification. No new matter is introduced by any of the amendments herein.

Upon entry of this Preliminary Amendment, claims 1-23 are pending. Applicants respectfully submit that claims 1-23 are directed to patentable subject matter. Accordingly, Applicants request allowance of the claims.

Authorization is hereby given to charge any fee in connection with this communication to Deposit Account No. 23-1703.

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Respectfully submitted,

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Claims 1-18 and 20- Version with markings to show changes made

1. A method of preparing homogeneous microparticles comprising [containing] a pharmaceutically active substance, wherein the method uses [by use of] a spray freezing technique and comprises the steps of: [which method comprices]

a) [-] atomizing into droplets a liquid medium having a minimum dry content of 15% by volume and comprising:

i) [a)] a pharmaceutically active substance; [,]

ii) [b)] a polymer selected from the group consisting of water soluble polymers nd non - water soluble polymers, said polymer being present in an amount of at least 5 per cent by weight based upon the dry content of the medium; [,]

iii) [c)] a liquid in which the pharmaceutically active substance and polymer are suspended, dissolved or emulsified; [,] and

d) optionally a dispersing agent; [, selected from the group consisting of polymers, surfactants, other substances and mixtures thereof,]

b) [-] freezing the formed droplets; and

c) [-] sublimating the frozen liquid of the droplets to obtain dry, homogeneous microparticles.

2. The [A] method according to claim 1, wherein the polymer of the liquid medium constitutes at least 10 weight % [or more] of the dry content.

3. The [A] method according to claim 1, wherein the polymer of the liquid medium constitutes at least 15 weight % [or more] of the dry content.

4. The [A] method according to claim 1, wherein the dry content of the liquid medium is from 15 to 60 vol %.

5. The [A] method according to claim 1, wherein the dry volume content of the liquid medium is from 15 to 60 vol % and gives dry microparticles with a relative density of 15 to 60 %.

6. The [A] method according to claim 1, wherein the dry volume content of the liquid medium is from 15 to 60 vol % and gives dry microparticles with a porosity of [85 down to] 40 to 85 vol %.

7. The [A] method according to claim 1, wherein the liquid medium to be spray-frozen [freezed] is a suspension.

8. The [A] method according to claim 1, wherein the liquid medium to be spray-frozen [freezed] is a solution.

9. The [A] method according to claim 1, wherein the liquid medium to be spray-frozen [freezed] is an emulsion.

10. The [A] method according to any one of claims 1-9, [of the preceding claims] wherein the content of the pharmaceutically active substance is from 60 to 95 weight % [, preferably 75 to 90 weight %,] of the weight of the dried microparticles.

11. The [A] method according to any one of claims 1-9, [of the preceding claims] wherein the dry content of the medium is from 15 to 60 vol % and [with] the content of the pharmaceutically active substance is [being] from 60 to 95 weight % of the dried microparticles.

12. The [A] method according to any one of claims 1-9, [of the preceding claims] wherein the polymer and dispersing agent are [is] selected from the group consisting of [a] cellulose derivatives, [a] polysaccharides, [a] natural polymers, [a] synthetic polymers, [a] surfactants, and mixtures thereof.

13. The [A] method according to any one of claims 1-9, [of the preceding claims] wherein the polymer and dispersing agent are [is] selected from the group consisting of shellacs, waxes, nylon, stearates, lipids, paraffin, lignosulphonates, [polymers, surfactants, other substances] and mixtures thereof.

14. The [A] method according to any one of claims 1-9, [of the preceding claims] wherein the liquid in which the polymer is soluble is selected from the group consisting of water, tertiary butyl alcohol, cyclohexane, methylene chloride, methanol, ethanol and mixtures thereof.

15. The [A] method according to any one of claims 1-9, [of the preceding claims] wherein the droplets are frozen by a cold medium [is] selected from the group consisting of liquid nitrogen, liquid argon, liquid oxygen, and [or a cooled] solvents cooled [well] below the freezing point of the liquid in the suspension.

16. The [A] method according to any one of claims 1-9, [of the preceding claims] wherein the sublimation is performed by freeze-drying.

17. The [A] method according to any one of claims 1-9, [of the preceding claims] wherein the size distribution of the prepared microparticles is [are] in the range from 10 to 1000 μm.

18. Microparticles [when] prepared according to the method of any one of claims 1-9 [of claims 1-17].

19. The microparticles according to claim 18 further comprising a polymeric film coating.

20. The method according to any one of claims 1-9, further comprising the step of [A method of preparing homogenous microparticles containing a pharmaceutically active substance, the particles being coated with a polymer film coating, which method comprises a method as claimed in any one of claims 1-17 followed by] coating the microparticles with a polymeric film coating.